

MEMORANDUM TO: Andrea Kock, Director
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Office of Nuclear Material Safety and Safeguards

FROM: Jacob I. Zimmerman, Chief
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SUBJECT: WORKING GROUP RECOMMENDATIONS FOR BUILDING A SMARTER FUEL
CYCLE LICENSING PROGRAM

On April 26, 2019, the Division of Fuel Cycle Safety, Safeguards, and the Environment (FCSE), issued a Charter (Agencywide Documents Access and Management System [ADAMS] Package Accession Number ML19115A011) to collect and evaluate stakeholder input on improving the efficiency and effectiveness of the fuel cycle licensing program. The enclosed working group report provides the deliverable required by the Charter. This report includes specific recommendations for each of the stakeholder suggestions and the qualitative prioritization of the proposed actions.

The anticipated next step is to develop an implementation plan that recommends how to address the interrelated suggestions and will include projected implementation timelines and resources. This plan will further inform division management decision-making in determining which, when, and how to implement the working group recommendations and the associated budget planning activities.

Enclosure:
Report for Building a Smarter Fuel Cycle Licensing Program

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RECOMMENDATIONS FOR BUILDING A SMARTER FUEL CYCLE LICENSING PROGRAM

PURPOSE

This report proposes recommendations to improve the fuel cycle licensing program. The U.S. Nuclear Regulatory Commission (NRC) staff developed these recommendations based on suggestions from both internal and external stakeholders. In providing these recommendations, this report completes the activities tasked under the Working Group (WG) Charter, dated April 26, 2019 (Agencywide Documents Access and Management System [ADAMS] Accession Number ML19115A016).

SUMMARY

While both the NRC staff and stakeholders largely consider the fuel cycle licensing program effective, both also recognize that further improvements could be gained. Through stakeholder correspondence and interactions, NRC staff insights, and input received during multiple public meetings, the WG collected thirty-two suggestions. Five of these suggestions have aspects that were considered separately by the WG, resulting in a total of thirty-seven suggestions being evaluated. The suggestions are wide-ranging, from relatively simple considerations, such as more frequent communication between the licensee/applicant and the NRC project manager; to relatively extensive actions, such as developing job aids for each aspect of the NRC staff review effort for various types of licensing actions. These suggestions, the associated WG evaluations, and the recommended actions are provided as Table 1 in the Attachment to this report. The WG has developed recommendations that are consistent with NRC's Principles of Good Regulation (PGR) (i.e., Independence, Openness, Efficiency, Clarity, and Reliability as defined in ADAMS Accession Number ML14135A076). These recommendations will continue to ensure the fuel cycle licensing program accomplishes its mission and strategic goals.

The WG evaluated the suggestions using a screening and prioritization process to bin the individual suggestions as high, medium, or low priority. This process first identified suggestions that are already established expectations and good practices. Based on their potential to reinforce certain PGR (e.g., clarity and openness) and/or improve the efficiency and effectiveness of reviews, the WG categorized these suggestions as high priority. The remaining suggestions were qualitatively evaluated for their potential to improve the efficiency and effectiveness of the fuel cycle licensing program in achieving the NRC mission. The WG then qualitatively evaluated the resources and time expected to implement each suggestion. The WG recommends that some suggestions, even though they may take significant resources and time to implement, be implemented in a phased manner. Table 2 of the Attachment to this report provides the prioritization of the recommendations for each suggestion.

The suggestions are grouped into three focus areas in the "Recommendations and Priorities" section of this report:

1. Guidance and Tool Development (3 high priority, 9 medium priority, and 3 low priority)
2. Planning and Processing (8 high priority, 3 medium priority, and 1 low priority)
3. Performance and Documentation (9 high priority, 1 medium priority, and 0 low priority)

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In addition, the WG determined it was more appropriate to address some aspects of the Charter during the implementation of suggestions, rather than during the evaluation and prioritization phase. These items are also discussed in the “Recommendations and Priorities” section of this report as additional considerations for implementation.

Through this initiative, the WG achieved the objective of the Charter by identifying, evaluating, and prioritizing thirty-seven suggestions for improving the fuel cycle licensing program. A wide range of suggestions was received from both internal and external stakeholders. The WG concludes that all suggestions are consistent with NRC's PGR, and therefore recommends that all the suggestions except one be implemented. The WG concluded that implementation of the suggestions will improve the fuel cycle licensing program in accomplishing its mission and strategic goals.

BACKGROUND

The fuel cycle licensing program applies to applications to construct, modify, or operate nuclear fuel cycle facilities licensed by the NRC under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40, “Domestic Licensing of Source Material,” and Part 70, “Domestic Licensing of Special Nuclear Material.” These include: nuclear fuel fabrication facilities, uranium enrichment facilities, uranium conversion facilities, greater than critical mass (GTCM) facilities, and medical isotope production facilities. The NRC staff's licensing reviews and decisions are performed using the concept of “reasonable assurance of adequate protection.” The guidance documents used in the fuel cycle licensing program include:

- “Division of Fuel Cycle Safety, Safeguards, and Environmental Review [FCSE]¹ Licensing Review Handbook” (LRH) (not publicly available), which assists project managers (PMs), technical reviewers (TRs), and supervisors by describing the steps, responsibilities, and expectations for performing licensing-related actions.
- NUREG-1520, “Standard Review Plan (SRP) for License Applications for Fuel Cycle Facilities,” (ADAMS Package Accession Number ML15176A258), which is a comprehensive and integrated document that identifies methods and approaches acceptable for meeting the NRC requirements and provides guidance to the NRC staff who perform reviews of applications to construct, modify, or operate nuclear fuel cycle facilities. NUREG-1520 addresses each of the technical disciplines involved in a review, including: the responsibilities of the NRC technical reviewer, the matters that they review, the Commission's regulations pertinent to the specific technical matters, the acceptance criteria used by the NRC staff, and the findings and conclusions that are appropriate to summarize the review.

In addition, on January 15, 2019, the Director of the Office of Nuclear Material Safety and Safeguards (NMSS) issued a memorandum to the NMSS staff on key principles for NMSS reviews (ADAMS Accession Number ML19015A290). The memorandum states that the scope of NMSS staff reviews should be adjusted in the following ways:

¹ In October 2019, the Division of Fuel Cycle Safety, Safeguards, and Environmental Review merged with the Division of Spent Fuel Management to form the Division of Fuel Management.

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- Focus NMSS staff resources and expertise on the most safety-significant portions of a licensing decision;
- Focus NMSS staff effort on reaching “adequate protection” or other regulatory conclusions based on reasonable assurance with respect to system performance, rather than an individual component; and
- Enable the NMSS staff to acknowledge that a new technology may be safer than an existing technology, although operating experience with that new technology may be lacking and the new technology may not meet the regulatory review standards developed for the existing technology.

The memorandum states that “[i]n line with this discussion of our optimal review approach to licensing actions, I have asked the division directors to engage you in discussions on the need for continued innovation and transformation in our work, including enhancing our use of risk insights in making a finding of reasonable assurance.” The enclosure to the memorandum includes additional information on “reasonable assurance of adequate protection” and describes various principles that should be considered in establishing the scope of licensing reviews, as well as performing and documenting the results of these reviews. Expectations for completing licensing actions for fuel cycle facilities in accordance with this memorandum were provided by the Director of the Division of Fuel Management (DFM) on January 24, 2020 (ADAMS Accession Number ML20010D837).

DISCUSSION

As stated in the memorandum approving the WG Charter (ADAMS Accession Number ML19115A017), the overarching objective of the WG is to perform a “... review of the Fuel Cycle Licensing Program for the purpose of improving the effectiveness and efficiency of the program.” The memorandum further states that the purpose of the WG is “... to conduct a holistic assessment of the Fuel Cycle Licensing Program to make recommendations on improving both the effectiveness and efficiency of the program while further integrating risk-informed insights.” To ensure that the WG benefited from recent risk-informed initiatives in other divisions and offices, the Charter identified specific NRC staff from the Division of Spent Fuel Management and Office of Nuclear Reactor Regulation (NRR) as members of the WG.

Although incremental changes to the fuel cycle licensing program have occurred, including a recent update of the LRH, the WG was specifically tasked to look for areas of transformation and innovation in the program while adhering to the PGR, which focus the NRC staff on ensuring safety and security.

Approach to Identifying Suggestions

The Charter specifically tasked the WG to solicit and assess feedback from internal stakeholders and a broad range of external stakeholders. The Charter also directed the WG to specifically review and consider a number of reference materials, including:

- The January 15, 2019, NMSS Office Director memorandum (ADAMS Accession Number ML19015A290);
- Associated licensing review guidance documents, such as the LRH and NUREG-1520;
- Findings from other related lessons learned and improvement activities, such as the Westinghouse Columbia Fuel Fabrication Facility Lessons Learned reports (ADAMS Accession Number ML16330A642);

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- Suggestions provided by external stakeholders during the development of the Charter, such as the NEI letter dated April 12, 2019 (ADAMS Accession Number ML19114A288) and the URENCO USA letter dated April 24, 2019. (ADAMS Accession Number ML19115A349); and
- Input and feedback from internal and external stakeholders.

As additional documents were identified (e.g., a recently issued NRR instruction), these documents were shared among the WG members for detailed consideration. In addition, the WG received suggestions via correspondence from external stakeholders. The documents and correspondence reviewed and considered by the WG are identified in the “References” section of this report.

Stakeholder input and feedback was vital to this initiative. To gather suggestions, five public meetings were held with interested stakeholders from April through November of 2019. These public interactions were coordinated with the similar initiative being pursued for the fuel cycle inspection program to ensure broad representation of potentially interested stakeholders. References to the public engagement activities can be found in the “Public Meetings” section of this report. In addition, insights and perspectives were received from fuel cycle project managers and technical reviewers via a “brainstorming” activity, one-on-one discussions, and suggestions received through the NRC staff innovation panel. Through this multi-faceted approach, the WG collected thirty-seven suggestions for improving the efficiency and effectiveness of the fuel cycle licensing program.

A. Approach to Prioritizing Suggestions

The WG evaluated each suggestion to determine its potential for improving the fuel cycle licensing program. Table 1 in the Attachment presents the thirty-seven suggestions along with the associated PGR, additional considerations identified by the WG, the WG’s recommended actions, and the priority determined by the WG.

The WG determined that only one suggestion should not be pursued further. That suggestion, Suggestion #6b, is related to providing information to the licensee/applicant on when, and the review metrics for, the Office of General Counsel (OGC) staff involvement in a review of a licensing action. While the WG agrees that general schedules should be provided to applicants/licensees, the WG did not agree that internal agency decisions such as what offices to involve in a review and the metrics for input from various members of a project, should be shared with the applicant/licensee. This is the only suggestion that the WG determined should not be pursued further.

To prioritize the suggestions, the WG devised a multi-step process. The approach considered if the action(s) needed to address the suggestion: was already an established expectation, would improve achieving the NRC’s mission, would result in licensing review efficiencies, and could be implemented effectively, considering both the time and resources it would likely take to implement the actions. The steps are described below.

Step 1: Determine if there is existing guidance or processes that already establishes an expectation that addresses the suggestion.

The first step identified suggestions that are already captured as an expectation or good practice within existing guidance or processes. The WG developed recommendations for

these suggestions taking into account the likely reason for the suggestion. Two common reasons identified by the WG are:

- The commenter was not aware of the NRC internal (i.e., non-public) processes or guidance, or
- There was an indication of the need to reinforce existing expectations and good practices.

The WG determined that some suggestions, especially those from external stakeholders, may have arisen because certain information (e.g., guidance documents) is not publicly available. For these suggestions, the WG recommends that materials be put in a form that can be shared publicly. Other suggestions indicate that, while guidance to address the suggestion exists, some NRC staff may not always implement the guidance as expected or leverage allowances within the guidance (e.g., good practices). For these suggestions, the WG recommends performing on-going knowledge management and training activities, including process and technical review seminars, job-specific training, and mentoring.

Twelve suggestions were identified in this step as already being an established expectation. While some of these suggestions may improve the efficiency and effectiveness of the fuel cycle licensing program, many are primarily associated with improving other aspects of the PGR, such as openness, clarity, and reliability. Based on these aspects of the PGR, the twelve suggestions were categorized as high priority and screened during this step.

Step 2: Consider the potential improvement in achieving the NRC's mission and improving the efficiency of the licensing program.

In the second step, the WG qualitatively evaluated the impact of the remaining twenty-five suggestions on mission effectiveness and efficiency. The WG first considered the potential improvement in achieving the NRC's mission, vision, and associated strategic goals, objectives, and strategies, as defined by the NRC Strategic Plan (ADAMS Accession Number ML18032A561). The WG then evaluated the potential improvement in the efficiency (a specific element of the PGR) of the licensing program if the suggestion was implemented. The WG qualitatively scored each of the suggestions as high, medium, or low in each area. Together, these two qualitative criteria form the second step of the screening process.

Step 3: Consider the likely resources and timing for NRC implementation of each suggestion.

In the third step, the WG qualitatively evaluated the suggestions considering the anticipated time and resources required to implement the specific suggestion. The timing and resource evaluations considered each suggestion individually; that is, the WG did not consider additional efficiencies or impacts from implementing multiple suggestions simultaneously. For timing, the WG qualitatively scored the suggestions as: high (minimal time, e.g., within 6 months), medium (some time, e.g., within 1 year), or low (significant time, e.g., greater than 1 year). For resources, the WG qualitatively scored the suggestions as: high (minimal resources, e.g., less than 0.5 FTE), medium (some resources, e.g., less than 1 FTE or contracting expenses), or low (significant resources, e.g., greater than 1FTE and/or contracting expenses).

During the performance of this step, the WG recognized that some suggestions may warrant phased implementation to fully achieve the intent of the suggestion. For example, Suggestion #30 suggested developing process and technical job aids based on lessons learned to guide all aspects of a review and for all types of applications. This suggestion could be better implemented in a progressive, phased manner. Some of these types of suggestions, while potentially scoring medium or low in resources and/or timing, are parenthetically indicated in Table 2 of the Attachment to this report as “phased.” Other suggestions that are indicated as medium or low in this step might also be considered for implementation in a phased manner or as resources allow.

Step 4: Final Prioritization

The results of the second and third steps were used by the WG to establish an overall prioritization of the twenty-five suggestions that had not been previously prioritized as high in Step 1. This process resulted in: eight suggestions prioritized as high, thirteen suggestions prioritized as medium, and four suggestions prioritized as low. The WG recommends that the suggestions prioritized as low only be pursued after accomplishing the high priority suggestions and/or as resources become available. Table 2 of the Attachment to this report presents the WG’s qualitative evaluation results and the final prioritization for each suggestion.

RECOMMENDATIONS and PRIORITIES

All the suggestions were subsequently grouped into three focus areas based on the primary means of implementation recommended by the WG. The matrix below identifies the specific suggestions by their primary implementation area and priority.

MATRIX OF SUGGESTIONS BY PRIMARY IMPLEMENTATION AREA & PRIORITY

Focus Area	High Priority Suggestions	Medium Priority Suggestions	Low Priority Suggestions
Guidance and Tool Development	19, 31, 32	14, 15, 20, 23, 24, 25a, 25b, 26, 30	10, 16, 17
Planning and Processing	1, 2, 3, 4, 6a, 7b, 18, 27	5, 28, 29	6b
Performance and Documentation	7a, 8, 9a, 9b, 11, 12, 13a, 13b, 21	22	

A. Guidance and Tool Development

A total of fifteen suggestions are primarily focused on improving or developing guidance and tools to further enhance the licensing program. Of these, three suggestions are considered high priority and all three suggestions (#s 19, 31, and 32) are already being implemented. Nine suggestions are considered medium priority and three suggestions are considered low priority. The priority grouping of the fifteen suggestions is as follows:

High Priority Suggestions

- #19 Providing training/seminars on the licensing program that highlights recent changes and long-standing fundamentals, including job aids, on-the-job-training opportunities, etc.

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- #31 Developing a job aid to support considering review phase “risk factors and their impacts” (i.e., risk considerations associated within specific phases of a review; including schedule risk and review/decision-making risks).
- #32 Harmonizing the NRC staff review guidance, procedures, instructions, and best practices within each of the prior divisions into the new, merged DFM.

Medium Priority Suggestions

- #14 Clarifying the focus of license renewal application reviews and performing a holistic review (e.g., “table top” exercise) with industry to identify additional lessons learned.
- #15 Incorporating concepts of NRR LIC-206, Integrated Risk-informed Decision-Making for Licensing Reviews,” into the fuel cycle licensing program guidance, in particularly the use of integrated review teams.
- #20 Developing guidance (e.g., SRP or job aid) for reviews of GTCM license applications.
- #23 Developing a business line instruction for license renewals.
- #24 Developing a catalog/roadmap for each type of license that identifies all the related fuel cycle licensing guidance (e.g., NUREGs, Branch Technical Positions, etc.).
- #25a Enhancing guidance to facilitate inspector insights and involvement in the licensing review process.
- #25b Developing a central repository for the current version of each license application and creating guidance/templates for uniformly profiling licensing basis documents in ADAMS.
- #26 Institutionalizing post-review lessons learned activities of new or complex applications to improve guidance and inform future new and novel application reviews.
- #30 Developing lower level process and technical job aids that incorporate risk insights and provides review discipline lessons learned, considerations in establishing the focus, scope, and level of effort for various types of applications, considerations in review sampling, etc.

Low Priority Suggestions

- #10 Establishing RAI timeliness metric considerations for application reviews in which RAIs are developed in a phased manner.
- #16 Moving the relevant information on performing license amendment reviews that is in non-public guidance into a business line instruction that is made publicly available.
- #17 Developing an automated tool to track licensing actions in accordance with NEIMA.

B. Review Planning and Processing

A total of twelve suggestions are primarily focused on review planning and processing (i.e., activities prior to a licensing action, such as pre-application meetings through the early

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processing phase of a licensing action through the acceptance for review phase). Of these, eight suggestions are considered high priority, including four suggestions (#s 1, 2, 3, and 6a) that are already established expectations. Three suggestions are considered medium priority. One suggestion is considered low priority. The priority grouping of the twelve suggestions is as follows:

High Priority Suggestions

- #1 Soliciting input from each licensee/applicant regarding milestones that should be established for each application review.
- #2 Sharing metrics and estimated level of effort with the licensee/applicant.
- #3 Updating the status of the review as it progresses, including the use of routine status calls between the NRC and licensee/applicant.
- #4 Meeting with the licensee/applicant during the acceptance review phase to better understand the unique aspects of the licensee's/applicant's request and identify complexities or unique aspects of the review.
- #6a Coordinating and sharing with the licensee/applicant the license application review milestones, considering the involvement of all support offices and centers of excellence (COEs).
- #7b Holding a site visit, especially for major license amendments, license renewals, and new applications, during the pre-application or acceptance review phases that includes all expected reviewers.
- #18 Ensuring internal work requests identify the appropriate NRC staff and that resource estimates are consistent with the projected scope, focus, and level of detail of each review area.
- #27 Enhancing the understanding of a proposed application by holding a meeting with the licensee/applicant, and possibly a site visit of expected core reviewers, during the pre-application phase and holding early integrated review team meetings to identify risk-informed considerations in setting the scope and focus of the review and identify any unique review considerations.

Medium Priority Suggestions

- #5 Encouraging combining multiple steps (e.g., acceptance and approval letters) of the review process for simple actions.
- #28 Revising guidance and associated metrics to allow combining review steps (e.g., acceptance review and formal NRC staff review) for expected short-duration and straight-forward license application reviews.
- #29 Improving, and incorporating into review guidance, the early processing, alignment, and documentation of the expected focus, scope, and level of detail of reviews and sharing this information with the licensee/applicant.

Low Priority Suggestions

- #6b Clarifying (and sharing milestones with licensees/applicants for) when OGC staff are involved in a licensing action review.

C. Review Performance and Documentation

A total of ten suggestions were determined by the WG to be focused on review performance and documentation (i.e., from formal initiation of the technical review through the request for additional information phase through documentation of the final SER). Of these, nine suggestions are considered high priority, including seven suggestions (#s 7a, 8, 9a, 11, 12, 13a, and 13b) that are already established expectations. One suggestion is considered medium priority. No suggestions are considered low priority. The priority grouping of the fourteen suggestions is as follows:

High Priority Suggestions

- #7a Holding a site visit, especially for major license amendments, license renewals, and new applications, at the draft RAI phase involving the pertinent reviewers.
- #8 Ensuring RAIs have a clear regulatory basis and leveraging existing job aids and templates to meet this expectation.
- #9a Discussing RAIs with the licensee/applicant in draft form to confirm understanding of the request and anticipated level of effort needed to develop the response.
- #9b Holding discussions with the licensee/applicant when a draft response to a RAI is developed to ensure the response appropriately addresses the NRC staff request.
- #11 Ensuring clarification calls with the licensee/applicant to support clarity and understanding of RAIs is not disincentivized by meeting notice metrics.
- #12 Using the tools (e.g., job aids and templates) available to the NRC staff to minimize the potential for multiple rounds of RAIs.
- #13a Ensuring the continuity of the quality, effectiveness, and efficiency of the licensing review process during NRC staff turnover.
- #13b Ensuring the continuity of the quality, effectiveness and efficiency of the licensing review process during NRC management turnover.
- #21 Providing guidance to ensure the Safety Evaluation Report (SER) documents the scope and focus of NRC staff reviews of licensing actions.

Medium Priority Suggestions

- #22 Using an electronic interface with licensees/applicants, including in support of review planning and implementation, such as for the RAI phase.

Low Priority Suggestions

NONE

D. Additional Implementation Considerations

The WG identified many suggestions that are interrelated or significantly overlap in scope. As a result, implementation of many suggestions should be integrated. For example, Suggestion #1 is related to soliciting input from the licensee/applicant in establishing review milestones for a licensing action. This suggestion significantly overlaps with Suggestion #6, which is related to establishing and sharing milestones with the licensee/applicant. Any action taken in this area should consider both suggestions together. Another example of interrelated suggestions involves twelve different suggestions (Suggestion #s 7, 8, 9a, 9b, 10, 11, 12, 13, 16, 22, 31, and 32) that have aspects that the WG identified as involving the RAI process. Implementation planning for improving the RAI process should consider all these suggestions in developing the path forward.

Finally, there are a few considerations and tasks identified in the Charter that the WG determined would be more appropriate to address during any implementation activities derived from this report. These additional considerations are discussed below, along with the recommended actions for the implementation phase.

Section II, Development of Implementation Metrics

The Charter directed the WG to develop metrics that would measure the effectiveness and efficiency of the implementation of the recommendations. At the time of this report the WG has not identified specific implementation metrics for each suggestion. Given the significant number of suggestions, the WG concluded that, where appropriate, implementation metrics should be established as part of an implementation plan. The metrics should consider: the scope of the suggestion(s), the expected level of long-term improvement in efficiency and effectiveness (or other PGR), the implementation approach (e.g., in a progressive phased manner, addressing related suggestions together, etc.), and the time and resources necessary for implementation. The NEI letter dated April 12, 2019, also addressed the need for implementation metrics as part of determining the success of the WG initiative and stated that this area warranted future dialogue as the initiative moved forward (i.e., General Comment 3). The WG concluded that engaging stakeholders, like NEI, after NRC management has approved the specific suggestions to implement will foster a more effective discussion of metrics.

Section III, Task E, Perform Table Top Exercises

The Charter directed the WG to perform, as appropriate, table top exercises of recent license amendments and license renewals to identify best practices, lessons learned, and insights into additional areas for improvements. The Charter also directed the WG to consider table top exercises for some potential improvements to determine their likely impact on program efficiency and effectiveness. In order to gather, evaluate, and address the numerous suggestions, the WG concluded that conducting table top exercises did not align with the scope and intent of this effort. However, the WG recognizes that future table top exercises may be beneficial for evaluating significant proposed changes to guidance. As an example, the

industry-provided Suggestion #14 essentially proposes conducting a table top exercise of recent license renewal applications to gain lessons learned, which could lead to improvements in NRC staff guidance and licensee submittals. The WG prioritized this suggestion as a medium priority. Since the next fuel facility license renewal application is not expected for several years, there is an opportunity to pursue such an endeavor, assuming continued interest and available resources.

Section III. Task G. Improvement or Development of New Performance Metrics

The Charter also directed the WG to develop recommendations for improving existing performance metrics and/or develop new performance metrics. The WG concluded that this task is embedded in a number of on-going NRC initiatives (e.g., NEIMA tracking and reporting related to Suggestion #s 10 and 17) and/or is expected to be part of the implementation of other specific suggestions. For example, the combining of steps of the licensing review process for straight-forward, short-duration reviews, as envisioned by Suggestion #s 5 and 28 would, by necessity, require milestones and performance metrics specific to the application. As a result, the WG did not provide any additional recommendations regarding performance metrics beyond what is captured within the proposed implementation actions of the associated suggestions.

CONCLUSIONS

Through this initiative, the WG achieved the objective of the Charter by identifying, evaluating, and prioritizing thirty-seven suggestions for improving the fuel cycle licensing program. A wide range of suggestions were received from both internal and external stakeholders via numerous interactions and correspondence. Many of these suggestions directly address the efficiency and effectiveness of the program, while other suggestions address the other PGR, such as openness, reliability, and clarity. Overall, the WG determined that the suggestions and recommended actions are largely consistent with NRC's PGR and their implementation will continue to ensure that the fuel cycle licensing program will accomplish its mission and strategic goals. As provided in Table 1 of the Attachment, the WG recommended specific actions for thirty-six of the thirty-seven suggestions. A total of sixty-seven recommended actions were identified by the WG. This completes the activities of the WG tasked under the Charter.

REFERENCES

Office of the Federal Register, Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40, "Domestic Licensing of Source Material."

Office of the Federal Register, Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material."

NEI, "Industry Comments on U.S. Nuclear Regulatory Commission Draft Working Group Charters on Building Smarter Licensing and Inspection Programs for Fuel Cycle Facilities Discussed During April 2, 2019 NRC Public Meeting," April 12, 2019. (ADAMS Accession Number ML19114A288)

NMSS, "Key Principles for Nuclear Material Safety and Safeguards Reviews," January 15, 2019. (ADAMS Accession Number ML19015A290)

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NMSS, "Process Improvement Project: Fuel Cycle Licensing Action Process Final Report," November 9, 2010. (not publicly available)

NMSS/DFM, "Licensing Process Expectations," January 24, 2020. (ADAMS Accession Number ML20010D837)

NMSS/FCSE, "Licensing Review Handbook," Revision 7, November 2018. (not publicly available)

NMSS/FCSE, "Westinghouse Lessons Learned Report," January 30, 2017. (ADAMS Accession Number ML16330A642)

NMSS/FCSE, "Westinghouse Additional Insights Report," March 31, 2017. (not publicly available)

NMSS/FCSE, "Working Group Charter for Building A Smarter Fuel Cycle Licensing Program," April 26, 2019. (ADAMS Accession Number ML19115A016)

NMSS/FCSE, Memorandum from Michael F. King to Jacob I. Zimmerman, "Approval of the Working Group Charter for Building A Smarter Fuel Cycle Licensing Program," April 26, 2019. (ADAMS Accession Number ML19115A017)

NMSS/SFM Division Instruction, SFM-2, Revision 2, "Safety Evaluation Reports," September 17, 2015. (not publicly available)

NMSS/SFST Office Instruction, SFST-3, Revision 4, "Requests for Additional information," August 19, 2010. (not publicly available)

NMSS/SFST Office Instruction, SFST-4, Revision 4, "SFST Licensing Process," April 14, 2009. (not publicly available)

NRC, "Achieving Modern Risk-Informed Regulation," SECY-18-0060, May 23, 2018. (ADAMS Package Accession Number ML18110A186)

NRC, "Strategic Plan - Fiscal Years 2018-2022," NUREG-1614, Volume 7. (ADAMS Accession Number ML18032A561)

NRC, "Principles of Good Regulations." (ADAMS Accession Number ML14135A076)

NRC, "Standard Review Plan for License Applications for Fuel Cycle Facilities – Final Report," NUREG-1520, Revision 2, June 2015. (ADAMS Package Accession Number ML15176A258)

NRR Office Instruction, LIC-101, Revision 5, "License Amendment Review Procedures," January 16, 2017. (ADAMS Accession Number ML16061A451)

NRR Office Instruction, LIC-107, Revision 2, "Procedures for Handling License Transfers," June 5, 2017. (ADAMS Accession Number ML17031A006)

NRR Office Instruction, LIC-109, Revision 2, "Acceptance Review Procedures," January 16, 2017. (ADAMS Accession Number ML16144A521)

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NRR Office Instruction, LIC-115, Revision 0, "Processing Requests for Additional Information," November 6, 2019. (ADAMS Accession Number ML19242B237)

NRR Office Instruction, LIC-206, Revision 0, "Integrated Risk-Informed Decision-Making for Licensing Reviews," June 10, 2019. (ADAMS Accession Number ML19031C861)

URENCO USA, "UUSA Comments on the NRC Proposed Charters, April 24, 2019. (ADAMS Accession Number ML19115A349)

PUBLIC MEETINGS

April 2, 2019, Public Meeting with Industry on Cumulative Effects of Regulation – Summary of Meeting. (ADAMS Accession Number ML19106A349)

May 21, 2019, Public Meeting on Building a Smarter Fuel Licensing and Oversight Program – Summary of Meeting. (ADAMS Accession Number ML19163A267)

August 8, 2019, Public Meeting on Building a Smarter Fuel Cycle Inspection and Licensing Program – Summary of Meeting. (ADAMS Accession Number ML19227A158)

September 25, 2019, Public Meeting with Industry on Cumulative Effects of Regulation and Fuel Cycle Regulatory Activities – Summary of Meeting. (ADAMS Accession Number ML19274D398)

November 15, 2019, Public Meeting on Building a Smarter Fuel Licensing and Oversight Program – Summary of Meeting. (ADAMS Accession Number ML19338C823)

March 5, 2020, Public Meeting on Building a Smarter Fuel Licensing and Oversight Program – Summary of Meeting. (ADAMS Accession Number ML20XXXXXX)

ATTACHMENT

REPORT TABLES

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Table 1 – SUGGESTION EVALUATION AND PRIORITY

#	Suggestion and Origin	Principle of Good Regulation	Additional NRC Considerations	WG Recommendation	Priority
1	<p>NEI (April 12, 2019 Letter; Specific Comment I.4 and I.5), NRC staff input, and public meeting discussions</p> <p>The current process for the NRC’s timeliness metrics for licensing actions should be analyzed for efficiency and effectiveness. Specifically, solicit input from each licensee/applicant regarding milestones that should be established for each application. Milestones may vary based on the complexity of the licensing action and estimated timeline.</p>	<p>Openness Reliability</p>	<p>The fuel cycle Licensing Review Handbook (LRH) already sets the expectation that the project manager (PM) will work with the licensee/applicant in establishing milestones for an application. The LRH also identifies effective communication of the PM with licensee/applicant staff and management as a vital activity. This suggestion is closely tied to Suggestion #6a.</p>	<p>PMs should continue the practice of soliciting input from licensees/applicants regarding the milestones for specific applications and sharing the established milestones with the licensee/applicant, consistent with Suggestion #6a.</p> <p>RECOMMENDED ACTIONS:</p> <p>1- Include topic in on-going knowledge management training. 2- As appropriate, convert licensing action process guidance into publicly available instructions.</p>	<p>HIGH</p>
2	<p>Industry public meeting discussions and NRC staff input</p> <p>Consider sharing standard metrics from Web Based Licensing (WBL) along with the hours estimated in the acceptance letter.</p>	<p>Openness Clarity</p>	<p>The LRH already notes that the PM should communicate the estimated hours for the review at the completion of the acceptance review and, consistent with Suggestion #1, the PM should interact with the licensee/applicant on establishing review milestones. Including the information in the acceptance review letter as currently implemented by fuel cycle PMs should continue.</p>	<p>PMs should continue sharing standard metrics and review hour estimates with licensees/applicants.</p> <p>RECOMMENDED ACTIONS:</p> <p>1- Include topic in on-going knowledge management training. 2- As appropriate, convert licensing action process guidance into publicly available instructions.</p>	<p>HIGH</p>

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3	<p>Industry public meeting discussions and NRC staff input Consider updating the status of the review as it progresses (i.e., encourage routine status calls between NRC and licensee/applicant). Licensees/applicants are planning capital projects, so the status of the reviews will allow them to keep their management informed.</p>	Openness	<p>The LRH already establishes the expectation for effective communication of the PM with licensee/applicant staff and management and identifies it as a vital activity. While periodic status calls between the PM and licensee/applicant are an established good practice, especially for large or more complex applications, the LRH does not explicitly address this type of interaction or recommend establishing the periodicity of these interactions with the licensee/applicant.</p>	<p>The review guidance (e.g., the LRH or other means) should be enhanced to establish the good practice and expectations associated with establishing regular status calls with licensees/applicants. Associated training for PMs should also emphasize the need to have agreed upon periodic status interactions (via teleconference, e-mail, or other communication means) with the licensee/applicant, considering the level of activity at the licensee/applicant. For large applications, this may involve routine status interactions focused solely on the application.</p> <p>RECOMMENDED ACTIONS: 1- Clarify the guidance that the PMs should hold periodic general status interactions with their licensee(s)/applicant(s) and to also hold periodic specific status interactions for large licensing actions. 2- Include topic in on-going knowledge management training. 3- As appropriate, convert licensing action process guidance into publicly available instructions.</p>	HIGH

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4	<p>Industry public meeting discussions and NRC staff input Consider a meeting with the applicant during the acceptance review to better understand the unique aspects of the licensee's/applicant's request and provide for early identification of complexities or unique aspects of the review.</p>	<p>Efficiency Clarity</p>	<p>The LRH states that pre-application public meetings should be encouraged for new licensing actions, particularly for new licenses or new processes for existing licenses. However, the guidance is not oriented on understanding the unique aspects or complexities of the licensee's/applicant's request. There is also no similar discussion for the acceptance review phase. This suggestion is similar to Suggestion #27 and relates to improving early staff alignment associated with Suggestion #29.</p>	<p>The review guidance should be improved to make it clear that when new, large, unique, or complex license applications are being considered by the licensee/applicant that the PM discuss with the licensee/applicant about holding a meeting to better understand the licensing action during the pre-application phase and/or the acceptance review phase. When considering whether to hold this type meeting the PM should consider the level of complexity of the licensing action. RECOMMENDED ACTIONS: 1- Enhance the review guidance for PMs to expand the intent and focus of pre-application meetings, leverage job aids supporting early interactions for improving review planning (see Suggestion #s 27 and 29) and provide the option to hold such meetings during the acceptance review phase. 2- Include topic in on-going knowledge management training. 3- As appropriate, convert licensing action process guidance into publicly available instructions.</p>	<p>HIGH</p>

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5	<p>NEI (April 12, 2019 Letter; General Comment 2b) and NRC staff input Combine the NRC acceptance and approval letters in one letter to the licensee/applicant in the case of simple license amendment requests.</p>	Efficiency	<p>This approach was recently implemented for a review and should continue to be used when appropriate, though it is not identified within the LRH as an option. This suggestion is similar to Suggestion #28. The current review metrics may disincentivize this approach if it results in missing an established metric (e.g., acceptance review within 60 days). If implemented, the licensing planning and tracking tool (i.e., WBL) would also need to be modified, which would involve contractor expenses.</p>	<p>The review guidance should be revised to encourage PMs to seek opportunities to improve review efficiencies by allowing flexibility within the review metrics (e.g., to exempt earlier due dates for combined steps) if overall efficiency is achieved (i.e., becomes outcome-oriented). The process and planning tools should be modified to support this flexibility. RECOMMENDED ACTIONS: 1- In concert with Suggestion #28, revise the review guidance related to work planning and metrics to encourage review efficiency approaches, such as combining review process steps for simple reviews that result in overall improvement in the review schedule. 2- Enhance the WBL tool to allow process steps to be combined (e.g., acceptance review and final SER) or skipped and the ability to adjust the metrics in these situations as long as the overall review is completed on an accelerated schedule.</p>	MEDIUM
6	<p>NEI (April 12, 2019 Letter; Specific Comment I.5), NRC staff input, and public meeting discussions a) Establish and share licensing milestones for most submittals to include all offices and centers of excellence (COEs) involved.</p>	Openness	<p>a) This suggestion is consistent with Suggestion #1, but is specific to the inclusion of support offices and COEs. The established practice is to share overall review milestones, but not to identify specific office or COE milestones.</p>	<p>a) RECOMMENDED ACTION: 1- Implement Suggestion #1, ensuring its implementation addresses the entirety of the review, including all offices and COEs involved in the review.</p>	a) HIGH

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	<p>b) Clarify (and share milestones for) when NRC’s Office of General Counsel (OGC) is involved with the review of a licensing action.</p>		<p>b) A representative from OGC discussed this aspect of the suggestion during the public meeting on August 8, 2019. Key review milestones typically do not go to the level of detail of providing specific office/COE review timeframes, but rather addresses the overall performance of the review by the NRC. The LRH provides guidance to the PM on the typical aspects that do not require (e.g., purely administrative) or do require OGC review (e.g., new licenses and license renewals).</p>	<p>b) While Suggestion #s 1 and 6a are recommended to be implemented related to establishing and sharing milestones with the licensee/applicant for the whole review, there is no expectation to share unique milestones for inputs or reviews by specific staff, branch, division, COE, or office. NO ACTION</p>	<p>b) LOW - NO ACTION</p>
7	<p>Industry public meeting discussions and NRC staff input Site visits are valuable, and the timing of the visits should optimize the NRC’s review a) with respect to requests for additional information (RAIs).</p>	Efficiency	<p>Site visits are valuable for staff unfamiliar with the facility or processes and for all staff to gain a fuller understanding of an application, especially for new, large (e.g., major license amendments, license renewals, and new applications) and unique/complex applications. a) The LRH already recommends scheduling a site visit shortly after draft RAIs are developed and the RAIs are provided to the licensee/applicant in preparation for the visit.</p>	<p>PMs should continue the good practice of coordinating a site visit at the appropriate time of review and should include supporting offices (e.g., NSIR and OGC), as appropriate. The ability to leverage “virtual audits/visits” using available technology, should also be recognized as an option. Also, consider the timing of the site visit: a) RECOMMENDED ACTIONS: 1- Include topic in on-going knowledge management training. 2- Further enhance the review guidance to ensure support office staff associated with a review are considered for a site visit and that opportunities to leverage available technology to perform a “virtual audit/visit is utilized when appropriate. 3- As appropriate, convert licensing action process guidance into publicly available instructions.</p>	HIGH

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	<p>b) prior to and/or after submittal (e.g., pre-application through early review phase).</p>		<p>b) The LRH does not address holding site visits at earlier phases and states it is generally scheduled after draft RAIs have been developed.</p>	<p>b) RECOMMENDED ACTION: 1- Provide additional review guidance, and associated training, to encourage holding a meeting at the site as part of a pre-application meeting or early in the review, especially for new, large, or unique/complex actions to gain insights and understanding of the scope of the application and of any unique or complex aspects.</p>	<p>HIGH</p>
8	<p>NEI (April 12, 2019 Letter; Specific Comment I.4), NRC staff input, and public meeting discussions The current process for the RAI process should be analyzed for efficiency and effectiveness. Specifically, the expectation should be established that an RAI have a clear regulatory basis. Consider if a uniform template is needed.</p>	<p>Clarity Efficiency</p>	<p>The LRH already establishes the expectation that RAIs have a clear regulatory basis, the guidance could be further enhanced by including templates and job aids. The importance of providing regulatory bases for RAIs has been communicated to the staff. A job aid developed for the spent fuel reviews could be leveraged to address this suggestion, especially in establishing a template for RAIs.</p>	<p>RECOMMENDED ACTIONS: 1- Develop a job aid and/or template (or refine the Spent Fuel job aid and template) for RAIs to further ensure consistency in providing the regulatory bases for RAIs provided and incorporate it into the review guidance. 2- Provide knowledge management and refresher training on when RAIs are needed or not needed and on the expectation that RAIs provide a clear regulatory basis. 3- As appropriate, convert licensing action process guidance into publicly available instructions.</p>	<p>HIGH</p>

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9	<p>NEI (April 12, 2019 Letter; Specific Comment I.4), NRC staff input, and public meeting discussions</p> <p>The current process for the RAI process should be analyzed for efficiency and effectiveness.</p> <p>a) Specifically, the expectation that an RAI be provided to the licensee first in draft form. Consider if RAIs should be discussed with the licensee/applicant in draft form to confirm understanding of the request, its significance to the application, and the expected level of effort/detail needed to address the issue.</p>	Efficiency	<p>The LRH already establishes a good practice to provide draft RAIs to the licensee/applicant to ensure understanding. This expectation was reinforced by the January 2020 DFM licensing expectations memorandum. These calls are expected to minimize the likelihood of multiple rounds of RAIs and improve the efficiency of the licensing process.</p> <p>This suggestion is also related to Suggestion #7a in that the LRH suggests holding a site visit after providing draft RAIs for larger applications to ensure full understanding.</p> <p>a) While, the LRH allows RAI clarifying calls, the purpose is narrowly set as ensuring understanding of the request and ensure a comprehensive response. The guidance could be more specific by stating that these calls serve to also clarify at a high level: the scope, significance, and level of effort expected by the staff request.</p>	<p>PMs should continue the practice of arranging discussions of draft RAIs with the licensee/applicant and for larger applications should consider scheduling a site visit (consistent with Suggestion #7a).</p> <p>a) RECOMMENDED ACTIONS:</p> <ol style="list-style-type: none"> 1- Enhance the review guidance to be more specific about the focus of the draft RAI clarifying calls to include discussions on the scope, significance, and level of effort expected of the licensee/applicant in responding to the request. 2- Provide knowledge management and refresher training on the use and purpose of clarifying calls with the licensee/applicant on draft RAIs. 3- As appropriate, convert licensing action process guidance into publicly available instructions. 	HIGH
	<p>b) In addition, also consider holding a discussion when the licensee/applicant has developed a draft response to ensure the response is appropriately addressing the staff request.</p>		<p>b) While the LRH has a sentence that states a call should be scheduled with the licensee/applicant to discuss the proposed RAI responses, no other guidance is provided. It is not clear that this good practice is implemented consistently, on a regular basis, or when a draft response has been developed.</p>	<p>b) RECOMMENDED ACTION:</p> <ol style="list-style-type: none"> 1- Provide more complete guidance and associated training for the PMs to arrange discussions with the licensee/applicant, especially for large applications or complex RAIs, when the licensee/applicant has developed draft RAIs to ensure the response fully addresses the staff request. 	HIGH

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10	<p>NRC staff input Consider when the clock should start on NRC's metrics surrounding RAIs.</p>	Clarity	<p>While the LRH states that the typical licensee/applicant is given 30 to 60 days from the date of the RAI letter, considering the complexity of the application and review, there is no stated metric for the staff in developing the RAIs. Further, such a metric would be different for different types of applications. The Nuclear Energy Innovation and Modernization Act (NEIMA) actions will likely influence how this item is addressed (see Suggestion #17). When implemented, the licensing planning and tracking tool (i.e., WBL) would likely need to be modified, which would involve contractor expenses.</p>	<p>RECOMMENDED ACTIONS: 1- Enhance the licensing planning and tracking tool (i.e., WBL) for the RAI portion of the review, in particular for the potential for RAIs developed in a staggered or phased manner. 2- Ensure metrics established for timeliness of RAIs are consistent with, or considered when, NEIMA metrics are established (see Suggestion #17).</p>	LOW
11	<p>NRC staff input Consider if the requirement to notice a public meeting 10-days in advance limits the benefit of discussing draft RAIs.</p>	Clarity Efficiency	<p>The LRH already establishes the good practice of holding RAI clarification calls (see Suggestion #9) without it needing to be a public meeting as long as the calls stay within the bounds of clarifying the meaning and intent of the RAIs. This can be very beneficial at the draft RAI stage to ensure the final RAIs are clearly communicated and understood by the licensee/applicant.</p>	<p>RECOMMENDED ACTIONS: 1- Include topic in on-going knowledge management training. 2- As appropriate, convert licensing action process guidance into publicly available instructions.</p>	HIGH

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12	<p>NEI (April 12, 2019 Letter; General Comment 2a and Specific Comment I.4), NRC staff input, and public meeting discussions RAIs should only be issued once the draft SER is written with each RAI addressing a gap in the draft SER. This should help minimize additional RAI rounds and would represent a significant, well-understood milestone in the review. Consider limiting the number of rounds of RAIs for certain types of licensing actions.</p>	Efficiency	<p>The LRH already establishes the good practice of developing the draft SER at the same time as the development of the RAIs, which are associated with gaps in the draft SER. The LRH further states that the review team should seek a single round of RAIs and subsequent rounds or follow-on RAIs should be avoided as much as possible. However, it is recognized that at times multiple rounds of RAIs may occur due to application complexities or other issues. As such, while there is an expectation to pursue high-quality reviews and RAIs that would limit follow-on or new RAIs, it is not appropriate to establish an a priori limit to the rounds of RAIs for a review. Addressing Suggestion #s 7 and 9 would also support achieving this goal of minimizing additional rounds of RAIs.</p>	<p>RECOMMENDED ACTIONS: 1- Implement Suggestion #s 7 and 9. 2- Incorporate into guidance the expectation that division management be engaged for subsequent rounds of RAIs. 3- Include topic in on-going knowledge management training. 4- As appropriate, convert licensing action process guidance into publicly available instructions.</p>	HIGH

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13	<p>NEI (April 12, 2019 Letter; Specific Comment I.6) Licensing Process Continuity: Based on industry’s experience, some processes and assurances need to be put in place to ensure continuity of quality and efficiency of the licensing process during a licensing action. This is particularly problematic with protracted and more complex licensing actions, e.g., renewals where additional documentation of status, next steps and other information to ensure a smooth transition from one staff or manager to another is needed. Need to address: a) staff turnover.</p>	Reliability Efficiency	<p>a) The LRH already establishes the expectation for effective PM and technical reviewer turnover, including the development of a transition plan and turnover package. In addition, the LRH states the draft SER inputs should be developed early in the review process (i.e., by the timing of the draft RAIs), which ensures more efficient development of RAIs (supporting Suggestion #s 7, 9, and 12) and also mitigates some impacts of staff turnover. Further, in skill areas where there is limited capability (e.g., no backup), proactive actions need to be taken to develop staff through mentoring, teaming, cross-training, double-encumbering positions, etc.</p>	<p>a) The importance of continuity of reviews has been communicated to the staff. Effective PM and technical reviewer turnover should continue to be an area of emphasis, including the use of transition plans. RECOMMENDED ACTIONS: 1- Implement Suggestion #s 7, 9, and 12 related to developing draft SER inputs at the RAI stage. 2- Include topic in on-going knowledge management training, specifically the use of transition plans and turnover packages. 3- Identify and increase the capability for critical skill areas where there is limited capability through technical mentoring, teaming, cross-training, double-encumbering positions, etc.</p>	a) HIGH

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	<p>b) management turnover.</p>		<p>b) While it is an implicit expectation and a good practice to have effective management (i.e., branch chiefs and above) turnover, there is no direct guidance describing the elements of effective management turnover, especially in the context of the continuity of licensing action reviews. Maintaining briefing books on the various licensees/applicants, types of facilities, and associated regulations, as well as up-to-date files describing the significant licensing actions, could mitigate some impacts of management turnover.</p>	<p>b) Steps should be taken to minimize the impacts of management turnover for currently active licensing action reviews. RECOMMENDED ACTIONS: 1- Develop a more formalized expectation and process related to the conduct of management turnover (e.g., establishing a management transition plan) that includes the status, actions, and discussions related to significant licensing issues and actions. 2- Develop a more formalized expectation that ensures continual up-to-date information is available for new managers, including: briefing books on the various licensees/applicants, their facilities and processes, licensing actions, issues, and the fuel cycle regulatory and licensing aspects. Consider the best means of maintaining this information up to date, such as being an established expectation of specific licensee/applicant PMs.</p>	<p>b) HIGH</p>

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14	<p>Industry public meeting discussions The current approved license provides a basis for acceptance review and limited NRC review for license renewals. This renewal application identifies program changes since last renewal. As such, license renewals should focus only on safety significant areas of change. This may result in needing no review for specific areas in which there are no changes to that program and no new/revised requirements. Also, consider a holistic review with industry input (e.g., table top exercise) on recent renewals to identify lessons learned.</p>	<p>Clarity Reliability</p>	<p>Depending on the type of staff review (e.g., programmatic, sampling, etc.), some reviews may be able to focus solely on the areas of change. However, other aspects, such as sampling type reviews, may involve additional sampling to confirm the accepted methods are being implemented appropriately. Even these aspects should focus primarily on areas of change. Implementation of Suggestion #23, which is related to developing guidance specific to license renewal, should directly address this suggestion and should use a holistic review with industry to enhance the guidance development.</p>	<p>RECOMMENDED ACTIONS: 1- Develop guidance (in concert with Suggestion #23) or a job aid (e.g., check list, questions etc.) specific to license renewals that describes what technical reviewers should consider in determining the proper scope, focus, and level of detail for their review (see Suggestion #29). 2- The above effort (and implementation of Suggestion #23) should also include internal lessons learned activities associated with recent license renewal reviews and a broader holistic review, such as a table top exercise, that includes PMs, technical staff, and licensees.</p>	<p>MEDIUM</p>

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15	<p>NEI (April 12, 2019 Letter; Specific Comment I.1), NRC staff input, and public meeting discussions</p> <p>The review level is adjusted based on available relative margin and the level of detail in the licensee/applicant submittal [and the staff level of review] should depend on that item’s level of safety and risk significance. Consider incorporating concepts from the recently issued NRR LIC-206, “Integrated Risk-Informed Decision-Making for Licensing Reviews,” into the fuel cycle licensing program.</p>	Efficiency	<p>A key concept that is directly implementable for larger team reviews is the use of integrated teams throughout the review.</p> <p>To be successful (i.e., efficient and effective) the guidance for an integrated review effort needs to ensure review teams hold regular team meetings throughout the review (including pre-application, acceptance, draft SER, RAI, and final SER phases, as appropriate) to ensure understanding of the application and consideration of relative risk insights in planning the review from an holistic perspective, the scope and focus of individual review areas, identifying unique considerations, and in conducting the reviews. The NRR integrated team review guidance, LIC-206, is available at: https://www.nrc.gov/docs/ML1903/ML19031C861.pdf.</p>	<p>RECOMMENDED ACTIONS:</p> <p>1- Incorporate into review guidance the use of integrated, multi-disciplined, review teams, especially for larger scope applications, leveraging existing guidance (e.g., LIC -206) and concepts such as “tiger-team” reviews, as appropriate, that work together either throughout the entire review or through specific phases of a review (e.g., review scoping).</p> <p>2- Develop job aids that inform the overall and individual review scope, focus, and level of detail. This job aid should consider a number of factors, including: type of application, scope of regulations, changes, prior application reviews, margin of safety, significance, uniqueness, complexity, precedence, etc.</p>	MEDIUM

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16	<p>Industry public meeting discussions and NRC staff input Consider developing an instruction for the Fuel Facility Business Line on license amendments like NRR's LIC-101, "License Amendment Review Procedures." This would take the relevant information out of the internal desk guide (fuel cycle LRH) and place it into a publicly available document that is applicable to all staff performing work under the Fuel Facility Business Line.</p>	Openness	<p>It is preferred to develop stand-alone guidance for the various aspects of the review that can be made publicly available without redaction (as would be needed for the LRH). The staff has already begun the development of an instruction for the RAI process, which needs to be coordinated and integrated with spent fuel instruction improvement efforts (see Suggestion #32)</p>	<p>The main focus of this suggestion is in taking the review guidance (i.e., the LRH) that is not currently publicly available and converting the appropriate portions of that guidance into a format (instructions or guidance) that can be made publicly available. RECOMMENDED ACTIONS: 1- Convert portions of existing review guidance (e.g., instructions specific to the development and resolution of RAIs) that is not currently publicly available into appropriate process-specific instructions or guidance that can be made publicly available. 2- Incorporate additional improvements to the converted guidance based on the implementation of related other suggestions of this working group report.</p>	LOW
17	<p>NRC staff input Develop an automated tool to track licensing actions in accordance with the new metrics associated with the Nuclear Energy Innovation and Modernization Act (NEIMA).</p>	Reliability	<p>There is already a working group associated with the DFM merger that is considering improvements to the WBL planning and tracking tool(s). The licensing tracking tool needs to be modified to enable this capability, which will involve contractor expenses.</p>	<p>RECOMMENDED ACTION: 1- Ensure that the revised WBL planning and tracking tool is able to address the NEIMA requirements.</p>	LOW

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18	<p>NRC staff input and public meeting discussions Ensure internal work requests identify the appropriate technical staff and that resource estimates are consistent with the projected scope, focus, and level of detail of each review area.</p>	Reliability	<p>Portions of this suggestion were recently implemented by fuel cycle PMs and should continue. Aspects of ensuring resources are consistent with established scope, focus, and level of detail of review should be further enhanced using risk-informed considerations. In particular, work on the item in the NMSS transformation action plan related to questions to consider during assignment and alignment on an activity should address this suggestion. This suggestion ties to better planning of reviews and ties to numerous other suggestions (e.g., Suggestion #s 2, 4, 15, 21, 27, 30, and 31).</p>	<p>RECOMMENDED ACTION: 1- Continue efforts associated with risk-informing the licensing action reviews through development of the assignment and alignment job aid/instruction and incorporate this guidance into the review guidance.</p>	HIGH
19	<p>NRC staff input Training on the licensing program, that highlights recent changes and longstanding fundamentals, should be provided for fuel cycle PMs and technical reviewers</p>	Reliability Clarity Efficiency	<p>This suggestion is already being performed and is expected to continue and expand in scope. Future seminars should consider including: How do specific technical reviewers perform their reviews? What are the review basics? What job aids and guidance exists?</p>	<p>There are already seminars being conducted. RECOMMENDED ACTION: 1- This continual learning and reinforcing of good practices should continue to be a high priority and used to maintain and expand capability and awareness of the staff.</p>	HIGH
20	<p>NRC staff input A standard review plan is needed for reviews of greater than critical mass licensees/applicants.</p>	Reliability Clarity Efficiency	<p>The current approach to these reviews is to follow aspects of NUREG-1520, but there is no specific guidance on which aspects to follow. This is not an efficient approach, especially as new reviewers join the organization. An old draft guide exists, however it was not finalized. This could be a starting point for any new guidance or job aid. This suggestion was also a recommendation of the lean six sigma activity performed in 2010.</p>	<p>Guidance specific to critical mass licensing would clarify and improve the consistency and efficiency of these reviews. RECOMMENDED ACTION: 1- Develop appropriate review guidance, specific to the review of critical mass license applications. The guidance could take the form of a SRP, instruction, review roadmap to NUREG-1520 (SRP), job aid, etc.</p>	MEDIUM

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21	<p>NRC staff input Document the scope and focus of licensing reviews in the Safety Evaluation Report (SER).</p>	Clarity	Current guidance does not explicitly require documenting this level of specificity of the staff reviews. This documentation could be especially valuable in ISA reviews and other areas involving sampling approaches (see Suggestion #14) and inform future reviewers of areas previously reviewed (or by implication not reviewed).	<p>RECOMMENDED ACTION: 1- Augment review guidance and provide associated training to ensure the specific scope, focus, level of depth and approach (e.g., sampling) used for the review are documented in the SER.</p>	HIGH
22	<p>NRC staff input Consider an electronic interface with licensees/applicants for RAIs, dashboards, etc.</p>	Efficiency	NRR is considering implementation of this practice. Lessons learned from these activities should be incorporated into any action considered by DFM. The main benefit may be achieved for larger or more complicated reviews or new types of applications.	<p>This may be a longer-term item that builds off lessons learned from NRR and past NRO.</p> <p>RECOMMENDED ACTIONS: 1- Establish a working group to evaluate the need and benefit of using a RAI and/or dashboard electronic interface for large-scope licensing action reviews. 2- Incorporate in review guidance or instructions the allowance for the use of this technology, as appropriate.</p>	MEDIUM
23	<p>NRC staff input Develop a business line instruction on license renewals.</p>	Reliability Clarity Efficiency	Implementation of this suggestion would directly address Suggestion #14	<p>RECOMMENDED ACTIONS: 1- Similar to Suggestion #20, and in concert with Suggestion #14, develop the appropriate type of guidance for license renewal applications, such as: SRP, instruction, review roadmap to NUREG-1520 (SRP), instruction, job aid, etc. 2- The above effort (and implementation of Suggestion #23) should also include internal lessons learned activities associated with recent license renewal reviews and a broader holistic review, such as a table top exercise, that includes PMs, technical staff, and licensees/applicants.</p>	MEDIUM

#	Suggestion and Origin	Principle of Good Regulation	Additional NRC Considerations	WG Recommendation	Priority
24	<p>NRC staff input Consider the development of a “licensing manual” to create a catalog of fuel cycle licensing guidance (e.g., NUREGs, Policy & Procedures, Branch technical Positions, generic communications, qualifications).</p>	<p>Reliability Clarity Efficiency</p>	<p>Many of the cited reference examples are available to the staff, though often scattered across multiple locations and platforms (e.g., SharePoint, ADAMS, internal website) and not consistently profiled in ADAMS. This suggestion also relates to Suggestion #25b.</p>	<p>RECOMMENDED ACTION: 1- In concert with Suggestion #25b, develop a roadmap for each type of license that identifies the appropriate regulations, guidance, procedures, job aids, etc. Consider creating a unique “catalogue” of references (or cross-reference lists) for each licensee/applicant or license type that is maintained by the appropriate PM and made easily available to the staff (e.g., SharePoint).</p>	<p>MEDIUM</p>
25	<p>NRC staff input a) Consider ways to better facilitate inspector involvement with the licensing process. How does an inspector raise a concern about a section of the license application?</p>	<p>Reliability Clarity Efficiency Independence</p>	<p>a) The LRH states that the PM should participate in frequent communications with regional counterparts regarding licensing activities at their facilities and provides an opportunity for inspector insights being shared at the draft SER stage. It is not clear that PMs routinely seek inspector insights into licensing actions. Further, there is not much guidance related to inspector direct involvement in the licensing review process. A similar recommendation was provided during the Westinghouse Lessons Learned activity.</p>	<p>a) The review guidance should be enhanced to establish the good practice and expectations associated with gaining the insights of inspectors in performing licensing action reviews. RECOMMENDED ACTION: 1- Incorporate into guidance that the PMs should facilitate inspector involvement in the licensing process to gain their insights at various stages of a licensing action, especially for large applications. This participation should not only be at the end of the review to ensure conditions etc. are understood and inspectable, but should also be early in the review to gain inspector observations that might aid in understanding and focusing aspects of the review. This interaction could be valuable for scoping and planning purposes at the pre-application and acceptance review stages.</p>	<p>a) MEDIUM</p>

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	<p>b) Can a central depository be developed for the current version of each license application? Are licensing basis documents uniformly profiled in ADAMS consistently? Can lessons be learned from NRR in how they maintain the licensing basis documents?</p>		<p>b) Developing a central depository and common profiling of licensing basis documents is similar to Suggestion #24.</p>	<p>b) RECOMMENDED ACTIONS: 1- Consistent with Suggestion #24, Consider creating a unique “catalogue” of references (or cross-reference lists), including licensing basis documents, for each licensee/applicant that is maintained by the appropriate PM and made easily available to the staff (e.g., SharePoint). 2- Ensure licensing basis documents are consistently profiled in ADAMS (e.g., use of a template for the various types of licensing basis documents).</p>	<p>b) MEDIUM</p>
26	<p>NRC staff input Can any efficiencies be gained that focus on the review of an application to: fabricate pebble bed reactor fuel; or produce medical isotopes? What about for amendments of current licensees/applicants to produce accident tolerant fuel?</p>	<p>Reliability Clarity Efficiency</p>	<p>This is a broad suggestion to leverage on-going efforts of continual learning, review lessons learned, and self-assessments to proactively prepare for new technologies and applications.</p>	<p>Lessons learned from previous large-scope applications that are new or novel should be performed to support review improvements for future new types of applications. RECOMMENDED ACTIONS: 1- Ensure current guidance is sufficient for expected near-term new applications, such as pebble bed fuel fabrication and medical isotope production. 2- Establish the expectation via guidance, procedure, or internal expectations memorandum that a lessons learned activity (or for smaller scope applications a “hot wash”) should be performed following the review of unique or complex applications to capture review insights and proposed improvements to guidance. 3- Integrate the lessons learned activity results into the DFM knowledge management and training activities.</p>	<p>MEDIUM</p>

#	Suggestion and Origin	Principle of Good Regulation	Additional NRC Considerations	WG Recommendation	Priority
27	<p>NRC staff input For the pre-application phase set expectations for holding early team meetings of likely technical reviewers and PMs to: understand proposed application, establish risk-informed considerations in setting early scope and focus of review in a holistic manner, and identify unique review considerations. Also, consider having a site visit (e.g., as part of a pre-application meeting with the licensee/applicant, especially for reviewers (including NSIR, OGC, et al) unfamiliar with the facility.</p>	<p>Clarity Efficiency</p>	<p>This suggestion ties to better planning and documenting of review effort and ties to numerous other suggestions (e.g., Suggestion #s 2, 4, 15, 18, 21, 29, 30, and 31). In particular, this action closely aligns with Suggestion #29 and is already being addressed per an action in the NMSS transformation action plan (see Suggestion #31) that involves developing questions to support assignment and alignment meetings. While this approach (either during pre-application or the acceptance phase) could increase the initial cost to the licensee/applicant and might require a slightly longer timeframe and metric if done at the acceptance review phase, efficiencies would likely be realized over the course of the review.</p>	<p>Continue activities to risk-inform the scope, focus, and level of detail of reviews. RECOMMENDED ACTION: 1- In concert with Suggest # 31 et al, improve the review guidance for the early phases of review planning so that there is a holistic approach in gaining early alignment on the expected scope, focus, and level of detail of reviews, considering any unique aspects of the review. The improvements should also include early documentation (including branch chief acceptance) within the PM process and communicated with the licensee/applicant. The process will also need to include a review revision process that includes the justification for changing these previously agreed upon aspects of the reviews.</p>	<p>HIGH</p>

#	Suggestion and Origin	Principle of Good Regulation	Additional NRC Considerations	WG Recommendation	Priority
28	<p>NRC staff input For reviews that are expected to be of short duration (e.g., < 60 days) and straightforward, forego the acceptance review phase (or have a minimal acceptance review (e.g., 2 days) with only a teleconference noting acceptance) and perform the technical review using an established timeliness metric for such reviews instead.</p>	Efficiency	<p>This approach was recently implemented for a review and should continue to be used when appropriate, though it is not identified within the LRH as an option. This suggestion is similar to Suggestion #5. The current review metrics may disincentivize this approach if it results in missing an established metric (e.g., acceptance review within 60 days). If implemented, the licensing planning and tracking tool (i.e., WBL) would also need to be modified, which would involve contractor expenses.</p>	<p>The review guidance should be revised to encourage PMs to seek opportunities for improve review efficiencies by allowing flexibility within the review metrics (e.g., to exempt earlier due dates for combined steps) if overall efficiency is achieved (i.e., be outcome-oriented). The process and planning tools should be modified to support this flexibility, such as providing a recognized path for short duration, straightforward reviews that do not need an acceptance review phase (or minimal acceptance review), such as applications that are solely administrative changes. RECOMMENDED ACTIONS: 1- In concert with Suggestion #5, revise the review guidance related to work planning and metrics to encourage review efficiency approaches, such as combining review process steps for simple reviews that result in overall improvement in the review schedule. 2- Enhance the WBL tool to allow process steps to be combined (e.g., acceptance review and final SER) or skipped and the ability to adjust the metrics in these situations as long as the overall review is completed on an accelerated schedule. and that metrics do not obstruct this efficiency.</p>	MEDIUM

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#	Suggestion and Origin	Principle of Good Regulation	Additional NRC Considerations	WG Recommendation	Priority
29	<p>NRC staff input Improve early processing, alignment, and documentation in establishing the expected focus, scope, and level of detail of reviews. Make this information available to the licensee/applicant.</p>	<p>Openness Reliability Clarity Efficiency</p>	<p>This suggestion ties to better planning and documenting of review effort and ties to numerous other suggestions (e.g., Suggestion #s 2, 4, 15, 18, 21, 27, 30, and 31). In particular, an action in the NMSS transformation action plan (see Suggestion #31) involves developing questions to support assignment and alignment meetings. As such, activities have already been initiated to address this suggestion. For example, a draft set of high-level questions have been developed to support review team early scoping activities.</p>	<p>Continue activities to risk-inform the scope, focus, and level of detail of reviews. RECOMMENDED ACTION: 1- In concert with Suggest # 31 et al, improve review guidance for the early phases of review planning so that there is early alignment on the expected focus, scope, and level of detail of reviews. The improvements should also include early documentation (including branch chief acceptance) within the PM process and communicated with the licensee/applicant. The process will also need to include a review revision process that includes the justification for changing these previously agreed upon aspects of the reviews.</p>	<p>MEDIUM</p>
30	<p>NRC staff input Develop process and technical job aids that augment the process and technical staff guidance at a lower level that incorporates: review area/discipline lessons learned and insights; typical considerations for determining the focus, scope and level of effort for different types of applications; considerations in review sampling approaches (if appropriate).</p>	<p>Reliability Clarity Efficiency</p>	<p>A working group has been formed to initiate work to address this suggestion. To capture the full scope and breadth of the suggestion would involve nearly every technical staff lead and many lead PMs. However, it could be initiated for what are considered the most significant areas of the typically more significant applications and then continued to other areas and application types as resources become available. This suggestion is closely related to Suggestion #31.</p>	<p>It is recognized that this action may need to be implemented in a phased and prioritized manner over a longer period as resources become available. RECOMMENDED ACTIONS: 1- Identify the highest priority areas and applications to develop process and technical job aids that will also be used to develop templates for future activities. 2- In concert with Suggestion #31, develop process and technical job aids to support risk-informing the reviews and decision making. The process and technical job aids should address each review discipline for each type of application, as resources become available.</p>	<p>MEDIUM</p>

#	Suggestion and Origin	Principle of Good Regulation	Additional NRC Considerations	WG Recommendation	Priority
31	<p>NRC staff input Develop a set of “risk factors and their impacts” (i.e., considerations) associated with specific tasks of a review; including schedule risk and review/decision-making risks.</p>	<p>Openness Reliability Clarity Efficiency</p>	<p>This suggestion was identified by NRC Innovation Panel Idea #68. One aspect (early alignment on activities) is associated with an action in the NMSS transformation action plan and is also related to Suggestion # 29. Activities have already been initiated to address this suggestion. For example, a draft set of high-level questions have been developed to support review team early scoping activities.</p>	<p>Continue activities to risk-inform review tasks. RECOMMENDED ACTION: 1- In concert with Suggestions #s 29 and 30, develop process and technical job aids to support risk-informed reviews and decision making as resources are available. Consider job aids that provide questions to ask to ensure every aspect of a review is appropriately risk-informed. For example, during pre-application and acceptance review, develop questions to aid in identifying the scope, focus, and level of detail of each review area and likely complex aspects of the review that might challenge the schedule; during development of RAIs, develop questions to aid in determining the best means for seeking information by call or formal request, the significance of information needed, and if the RAI should be elevated for management awareness.</p>	HIGH
32	<p>NRC staff input Given the recent merger of the divisions addressing fuel cycle facilities and spent fuel, staff review guidance, procedures, and instructions should be harmonized and best practices within each of the prior divisions implemented in a coherent manner within the new division.</p>	<p>Reliability Clarity Efficiency</p>	<p>This suggestion has already been identified as needing to be addressed as part of the DFM merger activities and activities are already underway to harmonize and incorporate good practices into review procedures and instructions. As an example, the initial activities on developing an instruction on RAIs (see Suggestion #16) should be integrated with the RAI lessons learned activities being addressed within the prior spent fuel division. A potential outcome is the development of a single RAI instruction that can be applied consistently across both business lines.</p>	<p>Continue merger activities related to harmonizing guidance and good practices in DFM guidance and instructions. RECOMMENDED ACTION: 1- Harmonize, incorporate good practices, and combine, where appropriate, the staff review procedures and instructions within DFM.</p>	HIGH

Table 2 – PRIORITIZATION OF SUGGESTIONS

Suggestion	Step 1	Step 2		Step 3		Overall Priority (H, M, L)
	Already Expected	Mission Improvement (H, M, L)	Efficiency Gain (H, M, L)	Timing Effectiveness (H, M, L)	Resource Effectiveness (H, M, L)	
1	Yes					H
2	Yes					H
3	Yes					H
4		M-H	M-H	H	H	H
5		M	M	M	M	M
6a	Yes					H
6b		L	L	L	L	L
7a	Yes					H
7b		M-H	M-H	H	H	H
8	Yes					H
9a	Yes					H
9b		M-H	M-H	H	H	H
10		L	L	M	M	L
11	Yes					H
12	Yes					H
13a	Yes					H
13b	Yes					H
14		M	M	L	M	M
15		H	M	M (Phased)	L	M
16		L	L	M (Phased)	M	L
17		L	L	M	M	L
18		M	M-H	H	H	H
19	Yes					H
20		H	M-H	M	M	M
21		M-H	M-H	H	H	H
22		M	M-H	M	M	M
23		M	M	L	H	M
24		M	H	M	M	M
25a		M-H	M-H	L	M	M
25b		M	H	M	M	M
26		H	H	L (Phased)	M	M
27		M-H	M-H	H	H	H
28		M	M	H	M	M
29		M-H	M-H	M	M	M
30		M-H	L-H	L (Phased)	L	M
31		H	H	H	H	H
32		H	H	M (Phased)	M	H

Table Entry Key:	HIGH (H)	MEDIUM (M)	LOW (L)
Mission Improvement	Significant Improvement	Some Improvement	Minimal Improvement
Efficiency Gain	Significant Gain	Some Gain	Minimal Gain
Timing Effectiveness	Near-Term (< 6 months)	Mid-Term (6 months to year)	Long-Term (> 1 year)
Resource Effectiveness	Minimal (< 0.5 FTE)	Some (0.5 - 1 FTE / contact \$)	Significant (> 1 FTE / contract \$)